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| 10/718,492 | 11/20/2003 | Christopher C. Toly | SIMU0004 | 8227 |
| 25268 7590 09/16/2009 LAW OFFICES OF RONALD M ANDERSON 600 108TH AVE, NE SUITE 507 BELLEVUE, WA 98004 | | | | |
| EXAMINER MUSSELMAN, TIMOTHY A | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/718,492

Applicant(s)

TOLY, CHRISTOPHER C.

Examiner

TIMOTHY MUSSELMAN

Art Unit

3715

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4-10, 14, 15, 17-41, 43, 44, 55-61, 88, 89 and 97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88 and 89 is/are allowed.
- 6) ☒ Claim(s) 2, 4-10, 14, 15, 17-41, 43, 44, 55-61 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Final Drawing Review (PTO-849)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/2/2009.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

In response to applicant's submission of 6/2/2009, claims 2-10, 14-15, 17-41, 43-44, 55-61, 88-89, and 97 are currently pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-10,14-15,17-41,43-44, and 57-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2 and 57 contain negative limitations wherein the system does *not* require an electrically conductive instrument configured to introduce an electrical current into the evaluation circuit, or a conductive instrument to close a gap between different segments of the circuit. Examiner is unable to find explicit support for this claimed negative limitation in the specification. Thus, without an adequate written description, one of ordinary skill in the art would not be enabled to construct and use the invention as claimed. **Claims 3-10,14-15,17-41,43-44, and 58-61** rejected for their incorporation of the above through dependency.

Claim 97 contains the negative limitation wherein a gap between conductive segments of an evaluation circuit is eliminated "without applying pressure to the external surface of the simulated physiological structure". Examiner is unable to find explicit support for this claimed negative limitation in the

specification. Thus, without an adequate written description, one of ordinary skill in the art would not be enabled to construct and use the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 2, 7, 8-10, 14-15, 17-28, 31, 34-37, 43-44, 55-58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in combination with Weiss (US 2003/0051561).

Regarding claims 2, 55, and 57, Adams discloses a simulated physiological structure, comprising a conductive elastomeric evaluation circuit configured as a portion of the structure, wherein the circuit enhances realism of the simulated structure. See col. 7: 37-55. Adams discloses wherein the circuit provides an electrical signal relating to a procedure being performed. See col. 8: 1-10. The circuit of Adams is pressure activated, and does *not* require an electrical current provided by an instrument placed in contact with the evaluation circuit, or the use of an electrically conductive instrument to couple to portions of a circuit together (rather the system requires no instruments at all). Adams does not disclose wherein the conductive elastomer is self healing with respect to punctures, but rather the system of Adams requires a metal foil which would *not* be self healing. This of course is not an issue in the system of Adams, because the system is *not* designed for punctures at all. Regardless, one of ordinary skill in the art at the time of the invention, constructing the system of Adams, would have been capable of

considering other pressure sensing systems available at the time. One such pressure sensing system is the tactile sensing system of Weiss. Weiss discloses a flexible pressure sensitive surface comprising conductive elastomer elements transfer the electrical signals from the force sensors for processing. See paragraph 0018. One of ordinary skill in the art at the time of the invention would have been inclined to use such an elastomeric tactile sensing configuration in the system of Adams, because it would increase the realism of the overall system by removing the need for the metal foil, and also because it is an equivalent item to the pressure sensing configuration of Adams, and no unexpected results would arise from the substitution of metal conductive pathways with elastomer pathways, as taught by Weiss. See MPEP 2143.

Regarding claims 7, 14-15, and 17, Adams discloses wherein the application of pressure closes the evaluation circuit, and the absence of pressure opens the evaluation circuit. See col. 7: 37-50. This is also manipulation as per claim 17.

Regarding claims 8, 10, 18 and 19, Adams discloses the use of evaluation circuits comprising conductive elastomer portions as described above with regard to claim 2. The use of other accepted equivalent sensor types as claimed in claims 8, 10, 18, and 19, would have been obvious to one of ordinary skill in the art, because it would be the substitution of one element with art recognized equivalents. See MPEP 2143.

Regarding claim 9, Adams further discloses wherein the pressure sensing system acts as a resistance sensitive switch. See col. 7: 45-50.

Regarding claim 20, Adams discloses wherein the system comprises multiple evaluation circuits. See col. 8: 1-10.

Regarding claims 21 and 61, Adams discloses an indicator connected to the evaluation circuit. See col. 8: 11-27.

Regarding claims 22 and 23, Adams further discloses an indicator coupled to the evaluation circuit that provides a light (computer screen) indicating feedback, and a meter (applied pressure displayed on the screen). See col. 11: 4-47.

Regarding claims 24-25, 35-37, and 58-60, Adams discloses wherein the simulated structure is a human tissue structure comprising multiple elastomer layers, and wherein the pressure is sensed from pressure applied to the outside (i.e. the periphery). See col. 3: 62-68.

Regarding claims 26-28, 31, 34, and 56, Adams discloses wherein the pressure circuits comprise a 3D grid comprising most of the simulated structure. See col. 7: 28-35. Adams also discloses wherein the system interfaces to a computer. See col. 8: 11-27.

Regarding claims 43 and 44, Adams discloses wherein the simulated structure is a human tissue structure. See col. 3: 62-68.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in combination with Weiss (US 2003/0051561) and Takaya et al. (US 5,175,214).

Regarding claims 4-6, Adams discloses a system comprising a conductive elastomer evaluation circuit, wherein the circuit monitors the performance and records the results to an electronic memory. See col. 8: 11-27. Adams does not *explicitly* disclose wherein the pressure sensitive conductive elastomer portions of the circuit consist of various materials dispersed in an elastomer matrix. However, this concept was an established technique in the art of pressure sensitive conductive elastomers, as disclosed by the conductive elastomer product of Takaya, in col. 2: 6-12. It would have been obvious to one of ordinary

skill in the art at the time of the invention to utilize known types of pressure sensitive conductive elastomers for their intended purposes, as no unexpected results would ensue, because it would be using a known product for its intended purpose.

Claims 29-30 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in combination with Weiss (US 2003/0051561) and Eggert (5,853,292).

Regarding claims 29-30, Adams discloses as described above a system that utilizes conductive elastomer in a medical simulation system in a fashion that meets all of the limitations of claim 2. However, Adams does not disclose any fluid channels, with or without sensory elements in the walls of the fluid channels. However, Eggert teaches of the medical simulation concept of sensors in the walls of simulated arteries in col. in col. 5: 18-36. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the circulatory system wall detection of Eggert with the elastomer evaluation circuits of Adams, because this would have been a combination of concepts known in the art that would not work differently in combination than they did in isolation.

Regarding claims 32-33, Adams discloses as described above a system that utilizes conductive elastomer in a medical simulation system including as an evaluation circuit in a fashion that meets all of the limitations of claim 2. Adams fails to teach of a physiological control element being coupled to the evaluation circuit so that the processor uses the evaluation circuit to control the physiological control element, and wherein the control element includes a servo and a pump. However, Eggert teaches of these features in col. 4: 45-60. It would have been obvious to one of ordinary skill in the art at the time of the invention to include these mechanical feedback systems in the invention of Adams because this would have been a combination of concepts known in the art that would not work differently in combination than they did in isolation.

Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in combination with Weiss (US 2003/0051561) and Hamilton et al. (US 4,872,841).

Regarding claims 38-41, Adams does not disclose wherein the system comprises joints or bones. However, Hamilton discloses a medical simulation system wherein the system simulates a joint between bones (vertebrae in a spinal column), and the sensors are configured to detect proper alignment which indicates proper performance of a procedure. See col. 1: 30-50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use sensory elements as disclosed by Adams in other systems, such as Hamilton, because it would be improving the product in a manner established in the art by using sensory technologies with increased realism.

Allowable Subject Matter

Claim 88-89 are indicated as allowable, because the prior art does not teach or fairly suggest the removal of a non-conductive segment and the repositioning and coupling of conductive segments together to complete an evaluation circuit.

Response to Arguments

Applicant's remarks dated 6/2/2009 have been fully considered. Applicant's arguments are moot in view of the new grounds of rejection. Examiner apologizes for not telephoning applicant regarding remaining outstanding issues as was discussed in a brief phone conversation. However, the new issues, including the 35 U.S.C. 112, 1st paragraph issues, were believed to be sufficient enough to warrant an office action. Applicant is invited to call the examiner so that all outstanding issues may be discussed and potentially agreed upon prior to applicant's next submission to the office regarding this case.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY MUSSELMAN whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./
Examiner of Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715